農林水産省補助事業

米国食品安全強化法

「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」規則にかかる食品安全計画雛形（ドレッシング）＜英語原文＞

2017 年 3 月

日本貿易振興機構（ジェトロ）

農林水産・食品部　農林水産・食品課

シカゴ事務所

本資料は、2015 年 8 月 31 日に最終化、同年 9 月 10 日に公表された米国食品安全強化法「ヒトが摂取する食品に関する予防的管理措置についての最終規則」に関して、米国の弁護士事務所 Olsson Frank Weeda Terman Matz PC(OFW)に委託をして食品安全計画の雛形（ドレッシング）を作成したものです。

＜Olsson Frank Weeda Terman Matz PC(OFW)＞
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お役立ち度アンケートへのご協力のお願い

ジェトロでは、米国食品安全強化法（FSMA）への対応の参考とすることを目的に本調査報告書を実施しました。ぜひお役立ち度アンケートにご協力をお願いいたします。

◆本報告書のお役立ち度　（必須）

□役に立った　□まあ役に立った　□あまり役に立たなかった　□役に立たなかった

その理由をご記入ください。

◆本報告書をご覧になり、実際にビジネスにつながった例がありましたらご記入ください。（任意）

◆今後のジェトロの調査テーマについてご希望等がございましたら、ご記入願います。（任意）

◆貴社・団体名（任意）

◆お名前（任意）

◆メールアドレス（任意）

◆企業規模　（必須）　□大企業　□中小企業　□その他

FAX 送信先：03-3582-7378　ジェトロ農林水産・食品課宛

本アンケートはインターネットでもご回答頂けます

（ https://www.jetro.go.jp/form5/pub/afa/fsma ）

※お客様の個人情報につきましては、ジェトロ個人情報保護方針に基づき、適正に管理運用させていただきます。また、上記のアンケートにご記載いただいた内容については、ジェトロの事業活動の評価および業務改善、事業フォローアップ、今後の調査テーマ選定などの参考のために利用いたします。

【報告書名：米国食品安全強化法「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」規則にかかる食品安全計画雛形（ドレッシング）＜英語原文＞】

はじめに

本調査報告書は、2015 年 8 月 31 日に最終化、同年 9 月 10 日に公表された米国食品安全強化法「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」（PCHF）規則に関して、食品安全計画の策定のための参考資料として「ドレッシング（すりおろし玉ねぎドレッシング）」を例に作成した雛形である。

食品安全計画の様式は PCHF 規則では規定されていない。またそれぞれの施設によって設備や製品、製造工程などは個々に異なるため、本報告書に記載された内容はあくまで一例である。実際の事業者の食品安全計画は、この雛形に、施設固有の管理すべき危害や予防管理手順を修正・追加することによって、適切なものとなる点に留意いただきたい。

なお、ジェトロは他にも「冷凍チャーハン」「味噌」「まんじゅう」の雛形を作成しているので、参考にしていただきたい。

本調査報告書が米国食品安全強化法（FSMA）への対応の参考となれば幸いである。

2017 年 3 月

日本貿易振興機構（ジェトロ）
農林水産・食品部　農林水産・食品課
シカゴ事務所

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1.Overview

Preventive Controls Plan Overview

The United States Food and Drug Administration's (FDA) Preventive Controls for Human Food regulation provides a proactive and systematic approach to food safety. It is similar to other risk-based food safety programs such as the FDA low-acid canned food regulations, FDA Seafood HACCP regulations and the United States Department of Agriculture's (USDA) Food Safety and Inspection Service's (FSIS) HACCP regulations.

- Preventive control programs are structured to work in conjunction with, and be supported by, other relevant programs such as Good Manufacturing Practices (GMP), good agriculture practices and good transportation practices.
- A preventive controls plan incorporates controls that go beyond those that would be managed as Critical Control Points (CCP) in the traditional Hazard Analysis Critical Control Points (HACCP) framework. While CCP may be included (most commonly for process steps that are critical for the safety of the food), the preventive controls plan also includes controls for hazards related to food allergens, sanitation, suppliers and any other hazards requiring a preventive control. While CCP are associated with a maximum and/or minimum value, other preventive controls will use parameters and values that will not have a precise critical limit.
- Also, a deviation of some preventive controls may only require an immediate correction (such as re-cleaning a production line prior to start-up of production) rather than a formal corrective action that includes product risk evaluations and development of preventive measures. Moreover, the validation activities (demonstrating the controls actually work) may be less rigorous for some preventive controls than others such as those that would qualify as a CCP under a HACCP approach.
- The FDA regulation requires that the original records or true copies be retained for at least two (2) years after the date they were prepared. Records supporting the process and its adequacy, such as validation studies, must be retained as long as necessary to support the operation and then at least two (2) years after their use is discontinued. Other details may be found in the regulation.
- All records and documents must include information adequate to identify the plant or facility (*e.g.* name, and when necessary, the address of the plant or facility).
- If a facility identifies the need for a preventive control when it completes its hazard analysis, it must then also have a written **recall plan** (***see* Supp. #29** for an example of a recall plan).
- Good Manufacturing Practices (GMPs) are addressed in 21 C.F.R. Part 117, Subpart B. Areas addressed by the GMP regulations include personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, holding and distribution of human food by-products for use as animal food, and defect action levels. When doing a hazard analysis, it may be determined that some GMPs may need to rise to the level of a preventive control as it is determined that it is controlling a hazard. For example, if you run product containing wheat flour on a production line and then must change to run a product without wheat flour, you would need to clean the production line to ensure that no allergen cross-contact occurred and wheat was not still present on the line. In this case, the sanitation process would rise to the level of a preventive control.
    - For example, in the Grated Onion Process (*see* p.7 "Flow Chart"), some GMPs you would monitor during steps 1 – 11 are as follows:

        - Ensure receiving dock and warehouse doors are kept closed when not in use and that all dock brushes and seals prevent access by pests or rodents.
        - Ensure there are no uncovered or damaged containers of ingredients, products or product packaging.
        - Ensure all ingredients are stored correctly if they contain various types of allergens.
        - Ensure there are no uncovered glass bulbs or broken glass in the area.
        - Ensure all containers are properly labeled with ingredient statements and no unapproved items are stored in the same area as product (*e.g.*, cleaning chemicals).
    - During steps 12 – 18 where product may be open to the environment, the following GMPs may be monitored:
        - The overheads are monitored on a routine basis to ensure that there is no condensation that could drip into exposed product.
        - Ensure there is no loose paint or debris that could fall into product.
        - Ensure there are no loose nuts or bolts or other pieces of equipment.
        - Ensure that there is not product or ingredients left on the floor for extended times.
        - Ensure that trash is in proper containers and they are not overflowing.
        - Ensure that product does not remain in production areas for too long if the ingredients are temperature-sensitive and the production area is not refrigerated.
        - Ensure that personnel who are handling the product have on frocks and are wearing disposal gloves to prevent direct contact with the product.
        - Ensure that personnel do not wear jewelry in the production area and all personnel have hair restraints and beard nets if needed.
        - Ensure that all facility and/or room entries are kept closed and there is no ability for pests or insects to enter the area.
    - During steps 19-21, the following may be monitored:
        - Ensure that labels are correct on all boxes and shipping containers.
        - Ensure that boxes are not damaged and wooden shipping pallets are in adequate condition to prevent product damage.
        - Ensure that trucks are clean, not damaged, and free of debris, pests, and evidence of rodents prior to loading with product.
    - All individuals working in a facility or warehouse are required to have documentation on file that they have been training in the necessary GMP appropriate to the job they are performing, in addition to any food safety training, to ensure compliance with a facility's food safety plan (*see* 21 C.F.R. § 117.4).
- Supply Chain Preventive Controls – This is one type of a preventive control. When in a hazard analysis, it is determined that a supplier controls the identified hazard; a company must implement a supply chain preventive control. For example, if you are purchasing processed cheese for to put on top of a cooked omelet, the supplier is ensuring that the cheese has been processed using a lethality step to control the biological (pathogens) hazards. Since the supplier is controlling this hazard, as you are not cooking the cheese, you must put in place a supply chain preventive control program to verify that the

supplier is performing the lethality process acceptably. Supply chain preventive controls are identified at the receiving steps in a hazard analysis.

This generic plan was developed to serve as a guide. The document provides the framework for the development of a Preventive Control Plan for Grated Onion Dressing. This generic plan is not intended to be used "as is" for your plant specific preventive control plan. It includes the required steps from the regulations as well as recommendations by FDA.

Since each processor of Grated Onion Dressing needs to conduct a hazard analysis for their own unique operation, this provides resources to assist in the development of the plant-specific plan. The document includes suggestions (in red) where there are decision points in the process.

Additionally, there are suggested formats for forms included even though there is no specific format required by the regulation.

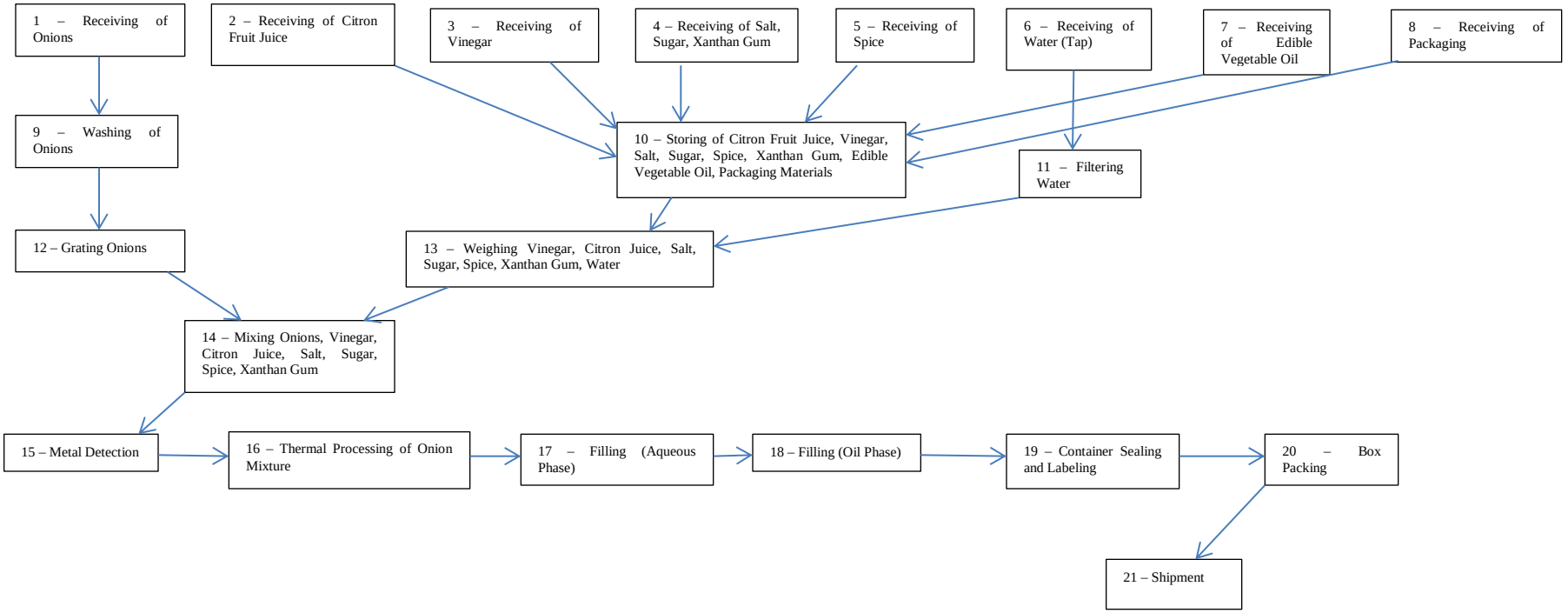
Examples include those identified below from the Supplements list. These procedures and records would be used in implementation of this food safety plan and may be used or modified for use in any facility. There is no regulatory requirement on how procedures or forms must look.

Examples include those identified in the list of Supplements as follows:

#22, Example – Employee Training Records
#23, Example – Storage Area GMP Audit
#29, Example – Generic Recall Plan
#30, Example – Reanalysis Form
#32, Example – Equipment Calibration Log
#36, Example – Corrective Action Record
#37, Example – Metal Detection Log
#40, Example – Batch Formulation Log

2. Flow Chart

Grated Onion Dressing
Flow Chart



3. Product Description

PLANT NAME(regulation requires that facility name, address be present on forms)	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Product Description Distribution, Consumers and Intended Use[1]

Product Name(s)	Grated Onion Dressing (Note: FDA has a Standard of Identity for salad dressing: http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=cb344532b54baa9e312a2bf2622196b6&ty=HTML&h=L&mc=true&n=pt21.2.169&r=PART)
Product Description, including Important Food Safety Characteristics	Shelf-stable, grated onion dressing; pH ≤ 4.6 (A general description of the product & processing method, assembly, & family of products included in the category. If it is relevant to product safety, properties like preservatives, water activity and pH should be listed here.)
Ingredients	Edible vegetable oil, vinegar, citron fruit juice, onion, salt, sugar, spice, xanthan gum, water (Assumed order of predominance – correct if inaccurate) (A list of ingredients, in order of predominance, which may be grouped or transferred from the product label.)
Packaging Used	Dressing is bottled in labeled polyethylene terephthalate bottles and caps. A polypropylene seal is used. Dressing bottles are placed in cardboard boxes for distribution. (A general description of the packaging, including units per box modified atmosphere or vacuum packaging if used)
Intended Use	Ambient temperature distribution for ready-to-eat consumption (Describe the normal expected use of the food (*e.g.*, ready-to-eat, raw), and where it is sold (*e.g.*, retail, food service, schools, hospitals, *etc.*). If an un-intended use is likely, this should also be identified (*e.g.*, eating product that contains raw eggs without cooking)).
Intended Consumers	General population (Food specifically designed for susceptible populations *e.g.*, hospitals, schools, may require more stringent controls because these foods will be consumed by an at-risk population.)
Shelf Life	Shelf life is 210 days. (List intended shelf-life.)
Labeling Instructions related to Safety	Refrigerate after opening. (Include label instructions relevant to food safety e.g., storage condition such as refrigeration, cooking instruction.)
Storage and Distribution	Stored and distributed at ambient temperature (List method of distribution *e.g.*, refrigerated, frozen)

Approved: Signature: Print	**Date**:

[1] Parameters involving quality should not be listed on the food safety product description. Quality parameters should be kept separate from the food safety preventative control plan.

4. Generic Preventive Controls Plan

Generic Preventive Control Plan
For Grated Onion Dressing

Facility Name:
Facility Address:

Product flowcharts must be edited to match the steps in the hazard analysis. As noted, we have added and made assumptions on some steps in the process. Each facility should ensure that the flowchart and hazard analysis match the steps in its process.

Plant Manager:

Plant Manager Signature:
(The preventive control regulation requires in 21 C.F.R. § 117.310 that the owner, operator or agent in charge of the facility, which could include, must sign and date the food safety plan upon initial completion of the plan and upon any later modification.)

ISSUED:
REVISED:

Preventive Controls Food Safety Team

(The team should consist of individuals with different specialties and experience with the facility's processes and procedures. The Food Safety team should include members who are directly involved with the plant's daily operations and may include personnel from maintenance, production (including equipment experts), sanitation, quality assurance, engineering, purchasing, and laboratory, if applicable. These individuals develop the food safety plan under the oversight of a Preventive Controls Qualified Individual, and verify on-going implementation of the food safety system.)

Examples of Participants on a Food Safety Team:

- General Manager
- Preventive Controls Qualified Individual (required) (Supp. #22)
- QA/Technical Service Manager
- QA Supervisor/HACCP Coordinator/Food Safety Manager
- Plant Superintendent
- Packaging Supervisors
- Purchasing Manager
- Processing Supervisors
- Kitchen Supervisors
- Logistics Manager
- Plant Engineer
- Plant Change Agent

PROCESS CATEGORIES AND INGREDIENTS*

(This form is useful to list out ingredients and categories of ingredients and other items used in product production. The ingredients listed below are examples of how a product could be broken into its components.)

Spices/Flavorings	Food Additives	Preservatives/Acidifiers
Spices	Xanthan Gum	Vinegar Citron Fruit Juice
Other	**Proteins**	**Packaging Materials**
Water** Onion Vegetable Oil*** Salt Sugar		Polyethylene Terephthalate Polypropylene Paper Cardboard
Allergens		

* All ingredients and suppliers of those ingredients should be evaluated prior to purchase of the respective ingredient to determine whether or not the ingredient and/or suppler has been involved in a food safety event such as a recall or an outbreak. The supplier and ingredient should be researched in databases relevant to the supplier and the source of the ingredient. For example, in the U.S. it would be expected that as part of a product evaluation into its safety, the Centers for Disease Control and Prevention's (CDC) "The Foodborne Outbreak Online Database" (https://wwwn.cdc.gov/foodborneoutbreaks/) would be reviewed as well as the Food and Drug Administration's (FDA) "Recalls, Market Withdrawals, Safety Alerts" (http://www.fda.gov/Safety/Recalls/) for any concerns that might involve the ingredient and/or the supplier of a respective ingredient. This information should be used in determining the likelihood of a particular hazard to occur.

** Water may or may not be used as an ingredient in product produced. Regardless, any water used for hand washing and sanitation should be potable. The facility should have in its files documentation on, at least an annual basis, that the water used in the facility meets regulatory requirements for potable use. This may be in a form of a letter from the local municipal water supplier stating the water being delivered to the facility meets all local and national standards and it details what those standards are and when it was tested.

***If the vegetable oil used is soybean oil, allergens must be addressed in the hazard analysis unless there is documentation that it is considered highly refined. *See* Supp. #33.

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REVISED:

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

HAZARD ANALYSIS

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
1. Receiving of Onions	B – *Salmonella*, *Listeria monocytogenes*, Shiga toxin-producing *E. coli*, *C. botulinum*, *Shigella*, *S. aureus*, *Giardia lamblia*	X		Pathogens may be present in raw produce. Receipt and storage of onion will be between 7-12 °C. (Supp. #1, 2, 3)	Process Preventive Control – subsequent thermal treatment step		X
	C – Radiological (Whether this is a hazard depends on where the onions are grown)	X		Radiological hazard may result from accidental contamination such as release from a nuclear facility or damage to a nuclear facility during a natural disaster (Supp. #4)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified auditor	X	
	C- Pesticides (If exporting product to the U.S. pesticides and their usage is regulated by the		X	No history of unapproved pesticides or findings of residual levels above tolerance that would require pesticides to be addressed as a supplier preventative control (Supp. #1, 5, 6) (Onions should be purchased from a grower/supplier that has good agricultural practices in place and is aware of			

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Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	U.S. Environmental Protection Agency (EPA), which establishes tolerance levels as well as what pesticide may be used.)			concerns and addresses issues such as those discussed in the Onion Production Guide page 46-48. *See* Supp. #24)			
	P - Foreign Material		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The Food Safety Team should address only those hazards reasonably like to cause injury.** (Supp. #7)			
2. Receiving of Citron Fruit Juice (Assuming the citron fruit juice has been thermally treated and shelf-stable.)	B – *Salmonella*, Shiga toxin-producing *E. coli*, *Listeria monocytogenes*	X		Acidic juices like citron juice may contain pathogens. Thermally treated citron juice is used so this hazard is unlikely (Assuming the citron fruit juice has been thermally treated and shelf-stable, if not this sentence should be removed.). In addition, any concerns are addressed at a later step in the process (Supp. #8, 9)	Process Preventive Control – subsequent thermal treatment step		X
	C – Economically motivated hazard	X		Economically motivated hazard (Supp. #10, 11,12)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified	X	

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No

	(While a rare occurrence, hazards may be introduced for purposes of economic gain. Only adulteration that affects food safety should be addressed in the Food Safety Plan. Examples have included the addition of melamine to dairy products in China. While this may be rare, it must be reviewed for each step in the process. Generally, economically motivated hazards are controlled though a supply-				audit		

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	chain program. You only must focus on economic adulteration that has a history of resulting in a hazard in food. Same can be said in following)						
	C- Pesticides (If exporting product to the U.S. pesticides and their usage is regulated by the U.S. Environmental Protection Agency (EPA) which establishes tolerance levels as well as what pesticide may be used.)		X	No history of unapproved pesticides or findings of residual levels above tolerance that would require pesticides to be addressed as a supplier preventative control (Supp. #5, 6)			
	P – Foreign material		X	Same as Step 1. "P - Foreign Material"			
3. Receiving of	B – None		X	Vegetative pathogens are unlikely to contaminate vinegar			

ISSUED:
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Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
Vinegar	Identified			(acetic acid). (Supp. #1)			
	C – Economically motivated hazard	X		Economically motivated hazard (Supp. #10, 11,12)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified audit	X	
	P – None Identified		X	No physical hazards are introduced or enhance at this step in the process.			
4. Receiving of Salt, Sugar, Xanthan Gum	B – Xanthan gum: *Salmonella*	X		Vegetative pathogens have been known to contaminate xanthan gum but can be controlled using a lethality process. Salt and sugar are not known to contain biological hazards. (Supp. #1)	Process Preventive Control - Subsequent thermal treatment step		X
	C - Unapproved Colors And Additives in Sugar and Salt		X	These ingredients are not known to be at risk for containing unapproved colors upon review of current import alerts. (Supp. #1, 31)			
	C – None Identified		X	These ingredients are not known to be at risk for containing a chemical hazard. (Supp. #1)			
	C – Economically motivated hazard	X		Economically motivated hazard (Supp. #10, 11,12)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified audit	X	
	P – None Identified		X	No physical hazards have been identified or enhanced at this step in the process.			
5. Receiving of Spice	B – *Salmonella*, Shiga toxin-	X		*Salmonella*, Shiga toxin-producing *E. coli*, *C. perfringens*, *C. botulinum*, and *B. cereus* spores have been known to	Process Preventive Control – subsequent thermal		X

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Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	producing *E. coli*, *C. perfringens*, *C. botulinum*, *B. cereus*			contaminate spices, especially pepper. Treated spices are used so this hazard is unlikely. However, any hazards are controlled at a later step in the process. (Suppl. #1, 13, 14, 15)	treatment step		
	C – Heavy Metals, Mycotoxins, Unapproved Colors And Additives	X		These ingredients are known to be at risk for containing unapproved heavy metals, mycotoxins, unapproved colors and additives upon review of current import alerts. The findings of residual levels above tolerance would require it to be addressed as a supplier preventative control. (Supp. #1, 31)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified audit	X	
	C – Economically motivated hazard	X		Economically motivated hazard (Supp. #10, 11,12)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified audit	X	
	P – None Identified			No physical hazards are introduced or enhanced at this step in the process.			
6. Receiving of Water (Tap)	B – *Campylobacter*, *Salmonella*, *Shigella*, *Vibrio cholera*, *Yersinia entercolitica*, Shiga toxin-producing *E. coli*, *Cyclospora*, Hepatitis A,		X	Biological hazards are potential contaminates of water. If well water is sourced, it should be tested at some frequency after in-house treatment to ensure it meets acceptable potable water standards. If water is obtained from a municipality, certificates of potability should be on file. (Supp. #16)			

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Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	SRSV						
	C – Radiological (Whether this is a hazard depends on where the water is sourced)	X		Radiological hazard may result from accidental contamination such as release from a nuclear facility or damage to a nuclear facility during a natural disaster (Supp. #4).	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified auditor	X	
	P – None Identified		X	No physical hazards have been identified in potable water.			
7. Receiving of Edible Vegetable Oil (If the vegetable oil used is a soybean oil, allergens must be addressed in the hazard analysis unless there is documentation that it is considered highly refined. See Supp. #33)	B – None Identified		X	Vegetative pathogens are unlikely to contaminate edible vegetable oil. (Supp. #1)			
	C – Mycotoxin	X		Mycotoxin production could occur during growth or primary process. (Supp. #1)	Supply Chain Preventive Control	X	
	C – Economically motivated hazard	X		Economically motivated hazard (Supp. #10, 11,12)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified audit	X	
	P – None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			
8. Receiving of Packaging (Container, Cap, Label)	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – Chemical Residues		X	Purchasing specifications require that all materials have on file a letter of guarantee from the manufacturer that states these products are approved for their intended use. (Supp. 17, 18)			
	P - None Identified		X	The storage area is reviewed to ensure that all products are properly stored in intact containers. (The facility should			

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Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
				have a GMP program that addresses proper storage of packaging materials. The program should include that the storage area is reviewed at some frequency. The program should include corrective actions that will occur is issues are identified. Personnel involved in ensuring proper storage of packaging materials should be trained in this procedure and that training should be documented. See Supp. #23)			
9. Washing of Onions	B – *Salmonella*, *Listeria monocytogenes*, Shiga toxin-producing *E. coli*, *C. botulinum*, *Shigella*, *S. aureus*, *Giardia lamblia*	X		Pathogens may be present in raw produce. (Supp. #1, 2)	Process Preventive Control – subsequent thermal treatment step		X
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – Metal	X		Pieces of metal may be introduced during the washing process. This can be controlled by subjecting the product to metal detection. (Supp. #19, 20)	Process Preventive Control – metal detection at subsequent step		X
	P – Foreign Material		X	Same as Step 1. "P - Foreign Material"			
10. Storing of Citron Fruit Juice, Vinegar, Salt, Sugar, Spice,	B - None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None		X	No chemical hazards are introduced or enhanced at this			

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Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
Xanthan Gum, Edible Vegetable Oil, and Packaging Materials (storage of onions after receiving is not addressed in the flowchart. If storage occurs, it needs to be addressed.)	Identified			step in the process.			
	P - None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			
11. Filtering of Water	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P –None Identified		X	While you indicate that filtering is done to remove foreign substances such as metal, rubber, and plastic, we find it difficult to comprehend that this would be in your water source and coming out of a water system. If filtration is done at this step to remove something such as calcium carbonate in the water, this would be considered a GMP process.			
12. Grating Onions	B – Vegetative Pathogens	X		Pathogens may be present in raw produce. (Supp. #1, 2, 3)	Process Preventive Control – subsequent thermal treatment step		X
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – Metal	X		Pieces of metal may be introduced during the grating process from equipment used. This can be controlled by subjecting the product to metal detection. (Supp. #19, 20)	Process Preventive Control – metal detection at subsequent step		X
	P – Foreign		X	Same as Step 1. "P - Foreign Material"			

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Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	Material						
13. Weighing Vinegar, Citron Juice, Salt, Sugar, Spice, Xanthan Gum	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – Foreign material		X	Same as Step 1. "P - Foreign Material"			
14. Mixing Onions And Vinegar, Citron Juice, Salt, Sugar, Spice, Xanthan Gum	B – Vegetative And Sporeforming Pathogens	X		The pH of the product will prevent and suppress growth. (Supp. #1, 34, 35) (There should be information on file to support that if the pH required to be met at this step is achieved; when the aqueous phases is mixed with the oil, the finished product will have a pH of ≤4.6.)	pH is ≤ ? (The pH of the finished product is ≤4.6. What is the pH of this mix? To have a final pH of ≤4.6, the pH at this step must be lower.)	X	
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – Metal	X		Pieces of metal may be introduced during the mixing process from equipment used. This can be controlled by subjecting the product to metal detection. (Supp. #19, 20)	Process Preventive Control – metal detection at subsequent step		X
	P – Foreign Material		X	Same as Step 1. "P - Foreign Material"			
15. Metal Detection (Magnet)	B – None Identified			No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified			No chemical hazards are introduced or enhanced at this step in the process.			
	P - Metal	X		Pieces of metal may be introduced during the process from equipment used. This can be controlled by subjecting the product to metal detection. (Supp. #19, 20)	Process Preventive Control – metal detection using a magnet	X	
16. Thermal	B – *Salmonella*,	X		Cooking the onion mixture to an internal temperature of ≥	Process Preventive Control	X	

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Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
processing of onion mixture (Heat sterilization)	*Listeria monocytogenes*, Shiga toxin-producing *E. coli*, *C. botulinum*, *Shigella*, *S. aureus*, *Giardia lamblia*			75°C and maintaining that product for at least one (1) minute will kill the vegetative pathogens. (Supp. #21) (The actual type of heat sterilization process is not indicated. The time and temperature parameters should match those required to address lethality for the process used.)	– Minimum internal temperature and hold time		
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			
17. Filling (Aqueous Phase)	B – *L. monocytogenes*	X		*Listeria monocytogenes* can be introduced to the product post-lethality exposure to the environment and cross contamination (Supp. #25, 26, 27, 28).	Sanitation Preventive Control – prevents contamination	X	
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – Foreign Material		X	No physical hazards are introduced or enhanced at this step in the process. GMPs are in place to ensure bottles are inverted to prevent any foreign material from remaining in the bottles prior to filling.			
18. Filling (Oil Phase) (When filling is complete, the two phases should be mixed to ensure the final pH is ≤4.6. Does this mixing	B - None Identified		X	Vegetative pathogens are unlikely to contaminate edible vegetable oil. (Supp. #1)			
	C - None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P - None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			

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Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
occur at filling?)							
19. Container Sealing And Labeling	B - None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C - None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P - None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			
20. Box Packing	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C - None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P - None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			
21. Shipment	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P - None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			

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Preventive Controls Plan

Process Control	Hazard	Preventive Control Parameters	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
Supply Chain Preventive Control – Receiving Spices	Heavy metals, Mycotoxins, Unapproved Colors and Additives	Received from an Approved Supplier approved on XX (date supplier(s) was approved, Supplier must be approved prior to receiving ingredients)	(Monitoring not required for supply-chain applied preventive controls.) (While monitoring is not required, there should be a procedure that identifies a Qualified Individual(QI) to review and document that each incoming shipment is received from an approved supplier.)				(The below are considered "corrections" as corrections may be used for minor and isolated problems that do not directly influence product safety.) The QI can reject shipments received from an unapproved supplier. Alternatively, the ingredient can be used in food for research only or other non-sales. The PCQI could make a determination to temporarily approve the supplier if adequate documentation is provided. The QI will determine the root cause and implement measures to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met.	Incoming Receiving Record Bill of Lading Copy of audit report by a qualified auditor obtained from the supplier Record showing use for research or non-sale item if applicable Correction/Corrective Action Records (Supp. #36) Reanalysis Form (Supp. #30)	PCQI ensures the reviews of the initial and annual audit of the supplier by the qualified auditor. PCQI ensures the reviews of the receiving record log within 7 days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) PCQI ensures the review of the corrections record within 7 days. (Considerations for appropriate verification can include: • What does the hazard analysis suggest about the nature of the hazard? • Are preventive controls applied by the supplier or the supplier's supplier? • What are the supplier's procedures, processes and practices related to safety for the ingredient or raw material? • Has FDA issued warning letters or import alerts related to the supplier's compliance? • Do your historical test or audit results for the supplier indicate a trend – positive or negative? • Have the supplier's corrective actions to past issues been appropriate and timely? • Are the supplier's storage or transportation practices appropriate?)

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Preventive Controls Plan

Process Control	Hazard	Preventive Control Parameters	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
Supply Chain Preventive Control – Receiving Edible Vegetable Oil	Mycotoxin	Received from an Approved Supplier approved on (date supplier(s) was approved, Supplier must be approved prior to receiving ingredients)	(Monitoring not required for supply-chain applied preventive controls.) (While monitoring is not required, there should be a procedure that identifies a QI to review and document that each incoming shipment is received from an approved supplier.)				(The below are considered "corrections" as corrections may be used for minor and isolated problems that do not directly impact product safety.) The QI can reject shipments received from an unapproved supplier. Alternatively, the ingredient can be used in food for research only or other non-sales. The PCQI could make a determination to temporarily approve the supplier if adequate documentation is provided. The QI will determine the root cause and implement measures to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met.	Incoming Receiving Record Bill of Lading Copy of audit report by a qualified auditor obtained from the supplier Record showing use for research or non-sale item if applicable Correction/Corrective Action Records (Supp. #36) Reanalysis Form (Supp. #30)	PCQI ensures the reviews of the initial and annual audit of the supplier by the qualified auditor. PCQI ensures the reviews of the receiving record log within 7 days. (While the regulation requires records review within 7 working days of completion; it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) PCQI ensures the review of the corrections record within 7 days. (Considerations for appropriate verification can include: • What does the hazard analysis suggest about the nature of the hazard? • Are preventive controls applied by the supplier or the supplier's supplier? • What are the supplier's procedures, processes and practices related to safety for the ingredient or raw material? • Has FDA issued warning letters or import alerts related to the supplier's compliance? • Do your historical test or audit results for the supplier indicate a trend – positive or negative? • Have the supplier's corrective actions to past issues been appropriate and timely? • Are the supplier's storage or transportation practices appropriate?)

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Process Control	Hazard	Preventive Control Parameters	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
pH of Aqueous Phase Of Product After Mixing	Vegetative and Sporeforming Pathogens	pH ≤ ? Add the limit for the pH of the aqueous phase.	Measure pH of product after mixing	Calibrated and accurate pH meter	Each batch of product	QI	The QI will ensure the product is uniformly mixed and that equilibration is complete. If product does not reach pH required, place product on hold. The QI will determine the root cause and implement measures to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met.	pH Log Equipment Calibration Log (Supp. #32) Batch Formulation Log (Supp. #40) Correction/Corrective Action Records (Supp. #36) Reanalysis Form (Supp. #30)	PCQI ensures review of documentation within 7 working days. (While the regulation requires records review within 7 working days of completion; it is highly recommended that this be done by on a daily basis. When issues are identified during the review, corrective action is required.) pH meter Verification (Accuracy and Calibration Checks)
Process Preventive Control - Metal Detection (Metal detection may occur at one or more steps in the process.)	Metal	Metal detector is present and operating and no metal fragments that would cause injury or choking are in the product that passes through the functioning metal detector.	All product passes through the functioning metal detector	Product passes through a functional metal detector which detects and rejects ferrous Y mm, non-ferrous –Y mm, stainless – Y mm.) (The company will have to support the size of the seeded samples used. The PCQI will oversee the validation and supporting material provided by the company for each step in the process.)	Hourly during production. (The company will have to support the frequency used.)	QI (A person who has the education, training, or experience (or a combination thereof)necessary to manufacture, process, pack, or hold, clean and safe food as appropriate to the individual's assigned duties)	A QI will take appropriate corrections or corrective actions (this includes actions to identify and correct the problem, action to prevent reoccurrence, all affected product is evaluated for safety, and all affected food is prevented from entering commerce is adulterated). The QI will determine the root cause and implement measures to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met. (In the event of an unanticipated food safety event, a re-analysis of the food safety plan or the appropriate portion of the plan would be required. Any re-analysis of the food safety plan must be done by a Preventive Controls Qualified Individual (PCQI). A PCQI is a Qualified Individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized by FDA or is otherwise qualified through job experience to develop and apply a food safety system.)	Metal Detection Log (Supp. #37) Validation records for setting and frequency Metal Detector Calibration Record Correction/Corrective Action Records (Supp. #36) Reanalysis Form (Supp. #30)	PCQI ensures review of documentation within 7 working days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) Verification will include the following: Direct observation of monitoring a minimum of once a week. The metal detector will be calibrated annually by the manufacturer to detect standardized metal slugs. (Note - The company could also use the recommendations of the manufacturer to have a different QI perform periodic calibration.)

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Process Control	Hazard	Preventive Control Parameters	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
Process Preventive Control - Thermal Processing Of Onion Mixture	*Salmonella, Listeria monocytogenes*, Shiga toxin-producing *E. coli, C. botulinum, Shigella, S. aureus, Giardia lamblia*	Cooking to an internal temperature of ≥ 75°C and maintaining that product for at least one (1) minute will kill the vegetative pathogens.	Internal product temperature is ≥ 75°C. and maintained at that temperature for at least 1 minute.	Calibrated and accurate thermometer	Each batch of product	QI	If the product temperature is not ≥ 75°C. and maintained at that temperature for at least 1 minute, the QI will ensure product continues to cook until the product meets the cook requirements. The QI will determine the root cause and implement measures to prevent reoccurrence. If finished product did not meet the minimum temperature and time requirements, the product will be reworked or destroyed. All parts of 21 CFR § 117.150(a)(2) will be met.	Cooking Record Equipment Calibration Log (Supp. #32) Correction/Corrective Action Records (Supp. #36) Reanalysis Form (Supp. #30)	The PCQI will ensure the review of all records within 7 days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) (Accuracy of thermometers is typically done on a daily basis using ice slurry or boiling water. Calibration of the thermometer is done periodically checking the equipment against an NIST standardized thermometer to ensure accuracy. (Supp. #38, 39))

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Process Control	Hazard	Preventive Control Parameters	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
Sanitation Preventive Control - Sanitation Of The Cooking Area, Cooling And Packaging Areas For Finished Products.	*Listeria monocytogenes* (*Listeria monocytogenes* can contaminate the product exposed to the environment after it has been cooked. This area requires special product handling, employee hygiene and sanitation. Many food companies have separate colored outer clothing, mops and cleaning supplies to prevent cross contamination with the raw product area. A separate document includes "Best Practices" that may be incorporated into a GMP.)	Prevent post-lethality contamination of product with *Listeria monocytogenes*	The cooking equipment/ area, cooling and packaging equipment/ areas are evaluated for cleanliness. Sanitizer strength is measured prior to application in the area *e.g.*, quaternary ammonium at 200 -400 ppm. All employees entering the area are wearing the designated outwear, hairnets and gloves.	Visual observation of the cooking equipment/area, cooling and packaging equipment/areas for cleanliness. Test strips are used to measure sanitizer strength. Employees entering the area are visually observed to be wearing the designated outwear, hairnets and gloves.	The cooking equipment/ area, cooling and packaging equipment/ areas are observed for cleanliness before start of operations. Sanitizer strength is measured prior to use. Employees in the area are visually observed for proper attire at start up, and every two hours during production.	QI	If the equipment/areas are observed unclean prior to operations, the operations are not permitted to start until the areas are recleaned and reinspected. If the sanitizer strength is not appropriate, it is remade or adjusted prior to using. If employees are not wearing appropriate attire for the areas, they are instructed to put on the appropriate attire. (It is important to note that the QI will need to assess whether the failure to wear proper attire may have led to potential cross-contamination of product.) If no product is involved, corrections will be taken. If product is affected, corrective actions will be taken that meet all requirements in 21 CFR § 117.150(a)(2).	Daily Sanitation Record Sanitizer Strength Record (Note- many companies include the sanitizer strength on the Daily Sanitation Record) Environmental Testing Program Records Laboratory Results Correction/Corrective Action Records (Supp. #36) Reanalysis Form (Supp. #30)	The PCQI will ensure review of all records within 7 days. (While the regulation requires records review within 7 working days of completion; it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) Environmental Testing Program (Environmental Testing applies to ready-to-eat foods that are exposed to the environment after processing and before packaging. The program should include the location and number of sites tested; timing and frequency of sampling; analytical method used; laboratory; and corrective action procedures for findings. An example Environmental Testing Program is included. Supp. #25)

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List of Supplements for Preventive Control Plan

1. Food and Drug Administration. 2016. "Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food, Appendix 1: Potential Hazards for Foods and Processes." Accessed October 19, 2016: http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517402.pdf.
2. Food and Drug Administration. 2010. "Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Valued-Added Unit Operations of Green Onions." Accessed October 19, 2016: http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM203114.pdf.
3. National Onion Association. Storage & Handling. Accessed October 19, 2016: https://www.onions-usa.org/retail/onions-fresh-market-retail-processing
4. World Health Organization. 2011. FAQs: Japan nuclear concerns. Accessed October 18, 2016: http://www.who.int/hac/crises/jpn/faqs/en/index7.html
5. Environmental Protection Agency. Regulation of Pesticide Residues on Food. Accessed October 18, 2016: https://www.epa.gov/pesticide-tolerances
6. Food and Drug Administration. "Guidance for Industry: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations". May 2005. Accessed October 18, 2016: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm077918.htm
7. Food and Drug Administration Health Hazard Evaluation Board, "CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects," 2005. Accessed October 18, 2016: http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074554.htm
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11. Everstine K., Spink, J., and Kennedy, S. 2013. "Economically Motivated Adulteration (EMA) of Food: Common Characteristics of EMA Incidents." *J. Food Prot*. 76(4): 723-735.
12. Michigan State University Food Fraud Initiative. "Food Fraud Reference Sheet." Accessed October 18, 2016: http://foodfraud.msu.edu/wp-content/uploads/2014/08/flyer-FF-Reference-Sheet-Final.pdf
13. Food and Drug Administration. 2014.Draft Risk Profile: Pathogens and Filth in Spices. Accessed October 19, 2016: http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM367337.pdf.
14. ICMSF. *Microbial Ecology of Food Commodities*. Second Edition. 2005. Vol. 6. Chapter 7 – Spices, dry soups and oriental flavorings. Kluwer Academic/Plenum Publishers. New York, New York. pg. 274-291.
15. Department of Health, Victoria, Australia. 2011 "Report on a Survey of Spices for the presence of Pathogens." A national survey conducted under the Coordinated Food Survey Plan with participation by

food regulatory agencies in Australia. Accessed October 19, 2016: http://www.health.vic.gov.au/archive/archive2011/foodsafety/archive/downloads/survey_spices.pdf
16. ICMSF. *Microbial Ecology of Food Commodities*. Second Edition. 2005. Vol. 6. Chapter 14 – Water. Kluwer Academic/Plenum Publishers. New York, New York. pg. 574-586.
17. Sample Letters of Guarantee for Packaging
18. USA, 21 CFR. § 7.13 Suggested Forms of Guaranty. Accessed October 19, 2016: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=7.13
19. Food and Drug Administration Health Hazard Evaluation Board, "CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects," 2005. Accessed October 18, 2016: http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074554.htm
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22. Example – Employee Training Records
23. Example – Storage Area GMP Audit
24. University of Georgia. 2014. Extension. Onion Production Guide. pgs. 46-48. Accessed October 25, 2016: http://extension.uga.edu/publications/files/pdf/B%201198-2_3.PDF.
25. Example – Generic Listeria Environmental Monitoring Program
26. Food Safety Preventive Controls Alliance. 2016 FSPCA Preventive Controls For Human Food Training Curriculum, Appendix 5. Version 1.2. pg. 495-504.
27. Food Safety Preventive Controls Alliance. 2016 FSPCA Preventive Controls For Human Food Training Curriculum ,Appendix 6. Version 1.2. pg. 507-526.
28. Swaim, J., 2016. "Requirement for *Listeria* Control Program and Best Practices to Control *Listeria*." Developed to provide summary of suggestions for controlling *Listeria monocytogenes* under the United States FDA and Preventive Controls for Human Food rule.
29. Example – Generic Recall Plan
30. Example – Reanalysis Form
31. Food and Drug Administration. 2016. "Import Alert 45-02: Detention Without Physical Examination and Guidance of Foods Containing Illegal and/or Undeclared Colors." Accessed October 20, 2016: https://www.accessdata.fda.gov/cms_ia/importalert_118.html.
32. Example – Equipment Calibration Log
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36. Example – Corrective Action Record
37. Example – Metal Detection Log
38. Flores, N.C., Boyle, E.A.E.. 2000. "Thermometer Calibration Guide." Kansas State University Agricultural Experiment Station and Cooperative Extension Service. Accessed October 20, 2016: https://www.asi.k-state.edu/doc/meat-science/thermometer-calibration-guide-2.pdf.

ISSUED:
REVISED:

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40. Example – Batch Formulation Log

5. Example - Training Document

Training

In addition to the Preventive Controls Qualified Individual(s), each facility will be required to have Qualified Individuals. Qualified Individuals are defined as "a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment." The Qualified Individuals should be trained for the job they are expected to perform at the facility and a copy of the training records should be maintained.

As a reminder, the Preventive Controls Qualified Individual (PCQI) is considered a qualified individual that has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system. The certification of the PCQI should also be maintained on file at the facility.

Example Training form

PRODUCT(S): Grated Onion Dressing		
PLANT NAME:	**ISSUE DATE:**	
ADDRESS:	**SUPERSEDES:**	

Training on Proper Sampling Technique for Environmental Monitoring – training conducted to ensure quality assurance personnel assigned to collect samples understand that a swab must be 30.5 cm by 30.5 cm and the goal is to identify the high risk part of the equipment for swabbing

Name	Signature	Date

6. Example - Storage Area GMP Audit

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

STORAGE AREA GMP AUDIT

STORAGE AREA	ACCEPT -ABLE	UNACCEP T-ABLE	CORRECTIVE ACTION
1. RETURNED GOODS: CONTROLED PROPERLY SPOILS INTO SPOILS CAGE.			
2. PALLET TRANSFER STATION FUNCTIONS			
3. GENERAL HOUSEKEEPING.			
4. GENERAL EMPLOYEES PRACTICES.			
5. COMBO BINS OF WOOD, CARDBOARD, MISC. GARBAGE TO BE DISCARDED WHEN FULL.			
6. TRANSPORT CARRIERS MUST BE ADEQUATELY PROTECTED.			
7. PROPER STORAGE AREA TEMPERATURE TO BE MONITORED DAILY			
8. SAFEGUARD ALL PRODUCTS AGAINST POTENTIAL LEAKS AND DRIPS AND NOTIFY PROPER PERSONNEL IMMEDIATELY.			
9. CLEAN UNDER PALLET FLOW RACKS AS NEEDED.			
10. MAKE SURE PRODUCTS ARE LOADED ON CLEAN TRUCKS.			
11. NO GUM CHEWING, JEWELRY, OR WATCHES IN DISTRUBUTION CENTER.			

AUDITOR _____ DATE _____

TIME_____

7. Example - Generic Recall Program

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Company Name Recall Program

Recall Plan

FDA requires a Recall Plan whenever the hazard analysis identifies any hazard that requires a preventive control.

The goals of a product recall

A product recall is intended to protect public health. Your first goal is to regain control of all potentially hazardous products. If this goal is met, the recall is successful. Sometimes you'll have to also work toward a second goal: telling the public about the potentially hazardous product and how to dispose of it.

Basic principles of conducting a product recall

There are basic principles that will make execution of your recall plan effective.

1. Use a lot or date code on all products.
2. Designate (ahead of time!) a person who will be in charge of the recall.
3. Designate (ahead of time!) a person who will talk with the media.
4. Keep good records of your wholesale customers so you can easily contact them.
5. Have a plan for informing the public.
6. Have model press releases and customer-contact scripts ready (ahead of time!).
7. Work with regulators.
8. Act quickly – if in doubt take the safer course of action.
9. Practice your recall plan with a "dry run."

PRODUCT RETRIEVAL POLICY

Company Name will maintain an effective warning and retrieval system for products that threaten public health, violate government regulations, or do not meet standards.

A. Introduction

Issued:
Revised:

Product recalls involve the removal of product from the market which are adulterated, misbranded, or otherwise in violation of federal/state statute or regulation. Recalls may be firm-initiated or USDA/FDA - requested. The term "recall" is used when there is reason to believe a product in commerce is adulterated or misbranded under the provisions of the Federal Meat Inspection Act, Poultry Products Inspection Act or Food Drug and Cosmetic Act. A Recall does not include a market withdrawal or stock recovery that is completed by the firm.

B. Recall Classifications:

Class I - This is a health hazard situation in which there is a reasonable probability that the product will cause serious adverse health consequences or death.

Class II - This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.

Class III - This is a routine situation where the use of the product will not cause adverse health consequences.

Market Withdrawals involve the removal of product from the market which are below quality standards or minor regulatory infraction that would not cause the product to be adulterated or misbranded.

Code Dates/Records

1. All products produced by. will have a legible code date that is produced by a code dating system which identifies the day and year of production.

2. **Company Name** will maintain all such records pertaining to product for no less than two years from production date.

D. Responsibilities

1. The decision to initiate a recall is the responsibility of the President or, in that person's absence, the General Manager. The decision to assume the responsibility for a recall activity previously initiated by a supplier/regulatory agency will be made by the President. The proper execution of a recall depends on the Recall Coordinator and the Recall Team, a standby group of personnel that is vital to the success of the recall action plan.

2. The Recall Officer directs all activities of the Recall Team, which is composed of the Recall Coordinator, and representatives of the following departments: (and hone fax and email for these individuals)

Department	**Representative**	**Alternative**
Recall Officer/Coordinator		
Marketing		
Legal		
Food Safety Team		
Plant Operations		
Preventive Controls Team/Quality Assurance		
IT/Accounting		
Call Center Operations		

The personnel and alternates assigned to the Recall Team are listed above. (**add real names and include only the people you will have on your team)**

.

The major responsibilities of the Recall Team are to:

1. Evaluate pertinent facts, information, and reports to confirm the degree of the hazard, the recall class, recall depth, and appropriate regulatory agency notification.
2. Create the form of written notification of the recall decision to use for all affected customers.
3. Notify distribution with instructions for the recall, including all product information and directives to stop shipments.
4. Develop a recovery force, which will prepare recall forms, conduct supplier notification and customer notification.
5. Establish lines of communication within the company, with the media, the insurance carrier, and with the appropriate regulatory agencies.

6. Prepare recall letters and press releases.

7. Implement effectiveness checks to verify receipt of all recall communications.

8. Maintain a log of all recall events.

9. Evaluate recall facts to assist in correcting errant manufacturing or distribution practices.

10. Identify and implement procedures for terminating the recall.

11. Evaluate the recall process to seek improvement in performing future recalls.

E. The responsibility of individuals and alternates on the Recall Team are as follows: **(*Define for your operations – these are ideas…)***

Recall Officer Responsibilities

1. Evaluate preliminary information concerning suspected health hazards, quality defects, or product adulteration, and obtain product samples, if necessary.

2. Coordinate efforts with Quality Assurance staff and food safety personnel to make a preliminary analysis of the suspected hazard.

3. If a health hazard is confirmed and the President decides to recall, call an immediate Recall Team meeting; coordinate and direct all activities of the recall procedure.

4. Coordinate and direct all activities involved in the disposition of recalled product.

5. Coordinate and direct all activities necessary to correct errant distribution practices.

6. Coordinate and direct internal communications.

7. In the event of regulatory agency involvement, participate in discussions and maintain records.

Recall Coordinator Responsibilities

1. Implement effectiveness checks.

2. Maintain a log of all recall events.

Marketing Responsibilities

1. In conjunction with the Recall Officer and Recall Team, prepare all external communications and function as media contact.

Legal Department Responsibilities

1. Ensure that a recall of product meets all applicable legal requirements.

2. Advise Recall Officer on appropriate actions to be taken to protect the rights of the company and its officials.

3. Review communications with regulatory agencies.

4. Assist in final drafting of information for release to the public.

Quality Assurance Responsibilities

1. Receive complaint information and document on Customer Complaint form.

2. Assist Recall Coordinator in making preliminary analysis of potential hazard.

3. Notify plant of initiation of recall action and stop production of suspect product.

4. Obtain all analytical lot information, lot records, product codes, ship dates, code dates, etc., to trace destination of suspect product.

5. Obtain suspect product sample when possible and arrange for shipment to designated laboratory for analysis.

6. Isolate documents and impound product at our facility, warehouse and distribution outlets.

7. Supervise and document the retrieval of suspect product from the customer.

8. Assist in isolating and impounding any raw materials or packaging components responsible for the product deficiency.

9. Confirm and document destruction of returned product if final disposition requires destruction.

10. Retain and provide security for any product samples or materials as requested by the Legal Department.

11. Execute an annual mock recall to assess effectiveness of procedures.

Sales and Call Center Responsibilities

(You may not have a call center- if a large recall and you do not – you may contract with someone to assist with calls… or you may need to increase the volume or your voice mail as you will receive a huge volume of calls and you do not want customers to think you are unavailable!)

1. Receive complaint information and document.

2. Assist Quality Assurance in obtaining product from customers when available.

3. Assist Quality Assurance in coordinating recall notification.

4. Document the dollar amounts payable to the customer.

5. Coordinate replacement of suspect product.

Accounting Responsibilities

1. Ensure that we have assessed and accounted for all costs associated with recall.

2. Ensure a timely recovery of all recall costs.

3. Advise Recall Officer of the status and extent of the supplier's insurance coverage.

4. Notify Company product liability carrier of the recall situation and keep carrier advised as necessary

ORGANIZATION AND COMMUNICATION GUIDELINES

A. Complaints: Notification of any physical illness or of any potentially serious product defect or complaint is to be communicated directly to the Recall Officer (or designee) and the Legal Department.

B. Preliminary Analysis of Hazard: If the Recall Officer, with the advice of the Quality Assurance and Legal Departments, determines that the complaint is an isolated instance, invalid, or does not involve any substantial hazard or quality defect, it is to be handled as a normal product quality complaint.

C. Product Recalls and Withdrawals: When there is reasonable evidence that a potential problem that could warrant a recall may exist, the findings are to be communicated by the Recall Officer to the President and the Recall Team. In consultation with legal counsel, the Recall Officer will recommend to the President actions to be taken, including what, if any, additional information needs to be developed and whether the appropriate regulatory agencies should be notified. The Recall Officer will continue to investigate the complaint to confirm the presence or absence of hazards or defects, utilizing all information available.

Decisions not to withdraw or recall a product are to be communicated internally to the Recall Team and to the regulatory agency involved (if such agency was

previously informed of the possibility of recall or withdrawal). Subsequent activity would then be the same as in handling a normal product quality complaint.

Decisions to recall will be communicated immediately to the Recall Team and to the appropriate regulatory agency. The Recall Officer will direct all recall activities as described previously. In the event of a recall initiated by a supplier or regulatory agency, the Recall Officer will immediately notify the Recall Team, and will direct all recall activities as specified in Recall Responsibilities of this manual.

D. Communication with Media and Customers:

(Practice this during mock recalls! Make sure phone lists are up to date. Make sure your employees know not to speak to the media. Have a friend show up in a van, wearing a suit holding a microphone and try to interview them on the way out the door. Will they answer questions????)

In the event of a recall, external communications with customers and the news media are critical to recalling the product and avoiding damaging publicity. Therefore, all communication with the media will be handled by Director of Marketing. All communications concerning possible recalls, stock recoveries or market withdrawals should follow company confidentiality guidelines. The Recall Team will approve all communications with customers. Where emergency situations exist, telephone, facsimile transmission, post cards or letters will be used in notifying customers and in locating product for return. To demonstrate that the company is acting in the customer's best interest, and to avoid publication of erroneous information, position statements will be prepared by the Director of Marketing for response to news media inquiries. Such information will be coordinated with the regulatory agency involved and given to the news media voluntarily. Accurate, timely communications with regulatory agencies is important; contact with the agency and release of information to the press will be made only when credible facts are available.

All internal communications regarding a recall and its progress are to be made by the Recall Coordinator and the Director of Marketing. Their statements will

describe the situation as it then exists. All calls from the media or the general public must be referred to Director of Marketing.

RECALL PROCEDURES

A. Receive Complaint: Customer complaints are normally directed to the Customer Service Representative for handling. If a potentially serious complaint is brought to the attention of the CSR, the Recall Officer and the Legal Department must be notified immediately. Documentation of all pertinent information as required. When available, suspect product will be obtained for shipment to designated laboratories.

B. Assessment of Public Health Significance: Based upon evidence and advice supplied by Quality Assurance and other departments, the President will determine the need to initiate immediate recall. In the event of any recall, the Recall Officer will order that all inventories of the product be impounded. The speed with which a product recall is put into effect is critical. Regulatory agencies require assurance that a recall will be carried out effectively and quickly.

C. Formal Notification of Regulatory Agency: The Recall Officer will notify the Recall Team when it becomes necessary to initiate a product recall. The Recall Officer will consult with legal counsel to ensure compliance with government regulations, and to determine company liability for seizures, injunctions, and prosecutions. When the decision to recall is made, the Recall Officer will communicate directly with the appropriate regulatory agency. The notice to regulatory agencies must include:

- Reason for recall
- Brand names
- Product names
- Packaging (Type & Size)
- Package codes (Use by/Sell by)
- Packaging dates
- Photos of label or package

- Case codes
- Count/case
- Production dates
- Distribution areas
- School lunch (yes/no)
- Department of Defense (yes/no)
- Internet or catalog sales (yes/no)
- Amount produced (pounds)
- Amount held at establishment
- Amount distributed (pounds/cases)
- Distribution level (depth of the recall, if known)

Copies of actual or proposed communication strategies and proposed recall strategies should also be shared with the agency.

Action Plan

1. Notification of potential problem.

2. Recall Team Group Meeting.

    a. Identify Problem - Recall officer

    b. Establish severity and magnitude - Team members

    c. Determine Scope of Recall by reviewing records

Distribution records are maintained as necessary to facilitate identification and location of products that are recalled. These records can be used to quickly provide FDA or USDA/FSIS with requested information regarding product distribution. Records such as bills of sale, invoices, and shipping papers are kept with respect to each transaction in which any livestock, poultry or poultry food, meat or meat food product purchased, sold, shipped, received or otherwise handled by the establishment in connection with any business subject to the FMIA or PPIA. These records include names and address of consignees, shipment method, date of shipment, etc.

    d. Decision of Action Mode - Recall Officer

    e. Clarification of objectives and assignments - Recall Coordinator

3. Action Mode

   a. Establish code date (s) of suspect product and total amount of product produced - Quality Control/Operations

   b. Establish location of all suspect product – Distribution

   c. Retain product in-house/Verify Quantity - Quality Control

   d. Notify customers/brokers/outside storage facilities to retain all suspect product/Verify Quantity – Distribution (Sample letters are attached that will be updated to include specific situations as necessary)

   e. Determine quantity of suspect product under retention (total available or under company control) - Quality Control-Shipping

   f. FDA notification – Class 1 recalls require a Reportable Food Registry report to be filed within 24 hours. All recalls should also include a notification to the local District Office to allow their input into recall.

   g. USDA notification- (USDA requires notification of recalls within 24 hours of initiating the recall) -Recall Officer

   h. Media coverage needed – Marketing Department

   (Media contacts reference in back of plan)

   i. Media Contact – Director of Marketing

4. Communication

   It will be the responsibility of each member of the recall Action Team to notify the Recall officer of any information obtained in indicating the possible need for product recall, market withdrawal, or stock recovery. This may be in the form of customer complaints, sales-broker comments, in-house findings, USDA or FDA notifications, etc. The Recall Officer will then make the decision as to whether a Recall Action Team meeting is needed.

   The initial meeting should be designed to either offer direction to group members as to information needed or to review information, identify real or potential problems, and formulate recommendation for action.

All information obtained thereafter should be forwarded to the Recall Coordinator. This information will be reviewed with the Recall Officer for reassessment of previous decisions and problem status.

5. Product Retrieval

Product is to be returned to a central or controlled location. Strict inventory of incoming suspect product must be maintained. Suspect product must remain under QC Hold tags until disposition decision has been made. Any condemnation of product should be supported with appropriate evaluation and testing by an independent agency. It is also recommended to obtain the assistance of an independent expert to verify that appropriate actions have been taken.

Procedure:

a. Designate location for return of suspect product.

b. Establish written handling procedures for suspect product. This should be submitted to FDA or USDA for approval. It must include sorting guidelines. This usually involves the categories: 1. Good product (acceptable for use under USDA and company standards.) 2. Questionable product (this product is either suitable for correction/reconditioning or subject to further testing, and 3. Condemned.

c. Designate person (s) responsible for supervision of suspect product receipt and handling.

d. Suspect product should be itemized by category (1,2,3 above)

e. Records for "Questionable Product" must be maintained. This product is to remain under QA Hold Tags until corrected &/or further testing results are available.

f. Condemned product is to be denatured as per USDA guidelines and records prepared and retained for all condemned products.

g. Condemned product could be sent to a landfill per USDA guidelines and approval.

6. Effectiveness Checks

The purpose of effectiveness checks is to verify that all consignee/customers involved in the recall have received notification about the recall and have taken appropriate

action. This is a means of assessing the progress and efficacy of a recall. FDA or FSIS will verify our effectiveness checks.

To assess the effectiveness of our recall, the recall team will compile the following information:

a. Pounds of each type of product implicated in the recall.
b. Labeling information for each product.
c. How much of the product is still "in house" or at other locations?
d. How many customers were affected?
e. How did we contact each customer?
f. Do we have documentation of the customers?
g. Do we have a written response acknowledging receipt of the recall information?
h. What actions were taken with the product? Who is responsible for these actions?
i. If the product was destroyed, was destruction witnessed and documented by responsible personnel? Were FDA/FSIS personnel present?
j. Do we have written documentation of
    1. When problem was identified?
    2. When customers were notified

7. Recall Assessment

The recall team will regularly report the results of the effectiveness of our efforts to retrieve the product to FSIS in order to keep them apprised of the status of recalls in progress. These reports will contain the following information unless otherwise specified:

1. The number of consignee/customers notified of the recall
2. The dates notifications were made
3. The method of notification
4. The number of consignee/customers responding to the recall communication
5. The quantity of product each consignee/customer had on hand at the time the communication was received.
6. The number of consignee/customers that did not respond
7. The quantity of product returned or held by each consignee/customer
8. An estimated time of completion of the recall.

8. Recall Conclusion

The recall will conclude when all the available portion of total suspect product produced has been located and handled appropriately as deemed necessary by FDA or FSIS and company guidelines. Refer to FSIS Directive 8080.1 Rev 4 Attachment 3

for the complete FSIS Recall effectiveness checks and recall termination requirements or FDA's Guidance for Industry: Product Recalls, Including Removals and Corrections for recall termination.

9. Recall Follow-up

   The recall team will evaluate the recall to determine whether things could be handled differently, and what if any improvements should be made to the plan.

   Further the Recall Team conducts a mock recall at least annually to verify the effectiveness of the plan.

Media Contact Information

Add local newspaper contacts and local media contacts – if you can get to know some one at these locations before a crisis – all the better!!!!

8. Example - Reanalysis Form

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

The FDA defines reanalysis of the food safety plan as "A verification procedure to assure that the Food Safety Plan remains valid and the food safety system is operating according to the plan". FDA requires a reanalysis at least every three (3) years; whenever a significant change in product or process occurs; when there is new information that becomes available about potential hazards associated with the food; when there is an unanticipated problem; and when a preventive control is ineffective.

Example Reanalysis Report

PRODUCT(S): Grated Onions Dressing		
PLANT NAME:	**ISSUE DATE**	
ADDRESS:	**SUPERSEDES**	

Food Safety Plan Reanalysis Report

(Add rows as needed if different plans are used for different products)

Checklist	**Date reviewed and initials of reviewer**	**Update needed Yes/No**	**Date Updated Completed:**	**Person (PCQI) Completing the Update** (initial of
List of Food Safety Team				
List of products and processes in place at facility				
Product flow diagrams				
Hazard Analysis				
Sanitation Preventive Controls				
Food Allergen Preventive Controls				
Process Preventive Controls				
Supply-chain Preventive Control Program				
Recall Plan				

9. Example - Equipment Calibration Log

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

EQUIPMENT CALIBRATION LOG

Equipment exists in the facility that requires periodic calibration. The frequency of calibration is dependent on the type of equipment used. **Direct Observation of the equipment being calibrated is indicated by the letters "D.O." and the initials of the person doing the direct observation in the space to the left of the "Date" column.**

* Dispose thermometer when adjustment is greater than 2°C.
* pH calibration slope range: 90.0- 105.0

Type of Equipment	Accuracy Check Frequency	Calibration Frequency
pH Meter	Daily	Daily
Water activity equipment	(per manufacture recommendations)	(per manufacture recommendations)
Thermometer	Daily	Quarterly
Portable Scales	Weekly	Yearly

Date	Time	ID for Equipment Calibrated	Water Activity Reading	Mercury Thermometer Reading (°C)	Thermometer Reading (°C)	pH Reading	Comments*	Operator Initials

Reviewed By: _____ Date:_____

Issued:
Revised:

10. Example - Corrective Action Record

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

CORRECTIVE ACTION REPORT

Date of Report: _____ Date of Incidence: _____

Preventive Control Deviation: _____

Description of **Deviation** (Include pounds, lot number and all details - ATTACH SEPARATE SHEET IF REQUIRED).

Document Completed By: _____

QA Personnel Notified: _____ Manager Notified: _____

Corrective Action Taken (To be completed by QA).

Prevention

Final **Disposition** of Affected Product

Signature & Date Required By:

Plant Manager: _____

QA Manager: _____

cc: Plant Manager, Director of Technical & VP Operations.

This corrective action response meets the requirements set forth in FDA Regulation 21 C.F.R. § 117.150(a)(2)
- ❖ Identify and correct the cause of the deviation,
- ❖ Action taken to reduce the likelihood the deviation will occur again,
- ❖ All affected product is evaluated for safety, and
- ❖ Prevent distribution into commerce of product adulterated as a result of the deviation.

Issued:
Revised:

11. Example - Metal Detection Log

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Metal Detection Log **Date: _____**

Time	Batch	Product	Metal Detector (Yes)	Visual Inspection	Initial	Corrective Action

Metal Detector Specifications: Y mm ferrous, Y mm non-ferrous. Y mm stainless. Frequency: ?
*Needs to be defined per specification

Supervisor (Name and Date): _____

Issued:
Revised:

12. Example - Batch Formulation Log

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Batch Formulation Log

Date:			
Product: Onion Dressing	Part No.		

Batch #	Pounds of Product (Actual amount)	Rec. Lot No.	Foreign Material?	Off Odor, Color, or Appearance?	Batch #	Pounds of Product (Actual amount)	Rec. Lot No.	Foreign Material?	Off Odor, Color, or Appearance?
Grated Onions			YES / NO	YES / NO	Grated Onions			YES / NO	YES / NO
Vinegar			YES / NO	YES / NO	Vinegar			YES / NO	YES / NO
Citron Fruit Juice			YES / NO	YES / NO	Citron Fruit Juice			YES / NO	YES / NO
Salt			YES / NO	YES / NO	Salt			YES / NO	YES / NO
Sugar			YES / NO	YES / NO	Sugar			YES / NO	YES / NO
Spice			YES / NO	YES / NO	Spice			YES / NO	YES / NO
Xanthan Gum			YES / NO	YES / NO	Xanthan Gum			YES / NO	YES / NO
Vegetable Oil			YES / NO	YES / NO	Vegetable Oil			YES / NO	YES / NO
Total Batch Wt.⇒		(Monitoring) Qualified Individual's Initials		Time	Total Batch Wt. ⇒		(Monitoring) Qualified Individual's Initials		Time

Batch #	Pounds of Product (Actual amount)	Rec. Lot No.	Foreign Material?	Off Odor, Color, or Appearance?	Batch #	Pounds of Product Actual amount)	Rec. Lot No.	Foreign Material?	Off Odor, Color, or Appearance?
Grated Onions			YES / NO	YES / NO	Grated Onions			YES / NO	YES / NO
Vinegar			YES / NO	YES / NO	Vinegar			YES / NO	YES / NO
Citron Fruit Juice			YES / NO	YES / NO	Citron Fruit Juice			YES / NO	YES / NO
Salt			YES / NO	YES / NO	Salt			YES / NO	YES / NO
Sugar			YES / NO	YES / NO	Sugar			YES / NO	YES / NO
Spice			YES / NO	YES / NO	Spice			YES / NO	YES / NO
Xanthan Gum			YES / NO	YES / NO	Xanthan Gum			YES / NO	YES / NO
Vegetable Oil			YES / NO	YES / NO	Vegetable Oil			YES / NO	YES / NO
Total Batch Wt.⇒		(Monitoring) Qualified Individual's Initials		Time	Total batch Wt. ⇒		(Monitoring) Qualified Individual's Initials		Time

Verification

Signature_____Date_____

Issued:
Revised:

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Monitoring and Verification procedures are detailed on the back of this document.

Monitoring: The Qualified Individual shall continuously monitor the ingredients as they are being added to the mixer. If the presence of foreign material is found or product is found to be off odor, color, or appearance or foreign material is identified, the Qualified Individual shall stop running product and notify management and document the finding. Management shall implement appropriate corrective action. (Management shall document immediate corrective action, including disposition of product, and measures to prevent reoccurrence on the Corrective Action Record.)

Verification: A Qualified Individual shall verify that the record has been completed correctly and any issues requiring corrective actions resulted in a Corrective Action Record.

米国食品安全強化法
「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」規則にかかる食品安全計画雛形（ドレッシング）＜英語原文＞

2017 年 3 月作成

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